AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

LISTING OF CLAIMS:

1. (currently amended) A method of performing interactive clinical trials for testing a new drug comprising:

a) performing a pre-clinical phase in which a computer model for pharmacokinetics and pharmacodynamics of the drug is created and adjusted based on in vitro studies and in vivo studies in animals;

b) performing a phase I clinical research in which a clinical trial on at least a single dose is performed in parallel with performing computer simulation studies using the computer model;

c) adjusting the computer model based on comparison of the results of the clinical research and the computer simulation;

d) determination of a maximal tolerated dose, minimum effective dose, and a recommended dose based on the phase I clinical research in conjunction with the computer simulations;

e) checking the drug for cumulative effects and providing this information to the computer model;

f) performing multiple simulations using the computer model with different doses and dosing intervals for different indications and patient populations;

g) determining, based on step f simulations results, an optimal ~~protocol~~regimen for the most responsive patient populations and clinical indications for a phase II clinical trial;

h) performing phase II clinical trial where a number of small scale clinical trials are performed in parallel based on results of step g;

i) analyzing interim results of step h, to choose the most promising regimens for continued clinical trials;

j) performing phase III clinical research for step g chosen clinical indications by step i chosen ~~protocol~~regimens;

j) performing phase III clinical research for step g chosen clinical indications by step i chosen ~~protocol~~regimens; and

k) performing phase IV studies for post-marketing subpopulation analysis and long term product safety assessment.

2. (original): The method of claim 1, wherein in step b, prior to each sub-step of the phase I trial, computer simulation is performed to predict results of the sub-step and the predicted results are compared to clinical results corresponding to the sub-step and the computer model is adjusted based on the comparison.

3. (currently amended): The method of claim 1, wherein prior to step h, a first decision whether to continue with the phase II clinical trial is made, stopping the trial if an adverse decision is made.

4. (currently amended): The method of claim 1, wherein results of step g are used to define clinical indications and define sub-groups of patients most sensitive, susceptible and responsive to the drug.

5. (currently amended): The method of claim 4, wherein effective treatment ~~protocol~~regimen is defined for a subset of the subgroups.

6. (original): The method of claim 1, wherein the computer model is adjusted based on whether the clinical research indicates a result higher than a threshold in at least one of pre-

clinical, phase I and phase II studies.

7. (currently amended): The method of claim 1, wherein in step h, the small clinical trials are performed in parallel for a chosen clinical indication by a chosen treatment ~~protocol~~regimen.

8. (currently amended): The method of claim 1, wherein in step i, the most promising trials are chosen for clinical indications most sensitive to the drug administered via the most efficient ~~protocol~~regimen.

9. (currently amended): The method of claim 8, wherein in step i, a second decision whether to continue with the phase III clinical trial is made, stopping the trial if an adverse decision is made.

10. (original): The method of claim 9, wherein the second decision is based on a prediction of safety profile of the new drug in the most promising trial compared with safety of pre-existing therapies.

11. (original) The method of claim 9, wherein the second decision is based on a prediction of efficacy profile of the new drug in the most promising trial compared with efficacy of pre-existing therapies.

12. (original): The method of claim 1, wherein step j is performed to prove safety of the drug.

13. (original): The method of claim 1, wherein step j is performed to prove efficacy of the drug.

14. (currently amended): The method of claim 1, when hithertounknown effects are discovered in step j, the computer model is adjusted to obtain predictions for new ~~protocol~~regimens, patient populations and clinical indications.

15. (original): A method of performing interactive clinical trials for a new drug comprising a step of performing a pre-clinical phase in which a computer model for pharmacokinetics and pharmacodynamics is created and adjusted based on in vitro studies and in vivo studies in animals.

16. (original): A method of performing interactive clinical trial for a new drug comprising a step of performing a phase I clinical trial wherein a dose-escalation trial is performed in parallel with computer simulation studies to predict results and the prediction is compared with clinical results and the comparing is used to adjust the computer model.

17. (original): A method of performing interactive clinical trials for a new drug comprising: developing a strategy for a next sub-step in phase I clinical trial in conjunction with simulated computer predictions.